

REMARKS

Claims 1-17 are currently pending in this application. Claim 1 has been amended. Support for the amendment can be found throughout the application but at least at page 4, lines 17-22. Applicants have also amended the specification to correct minor typographical errors. No new matter is presented.

Applicants note that the Examiner indicated that while the Declaration by Ubaldo Conte submitted on January 29, 2009 showed a difference in the release profile of the instant application and the cited art, the limitation was not found in the claims. Applicants have amended the claims to reflect the different release profile. The amended claims require the limitation that the tablet has a substantially constant active ingredient release rate.

35 U.S.C. § 102 Rejections Overcome

Claims 1-17 remain rejected under 35 U.S.C. §102(b) as allegedly being anticipated by US 5,487,901 and 5,650,169 (“Conte”). Applicants respectfully traverse the rejection.

In order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). Specifically, the Examiner states that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient formulated for immediate release, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an impermeable insoluble polymeric coating (*emphasis added*). (*See*, Office Action at pages 2-3). The Examiner concedes that the method by which the tablet of claims 1-17 is made is different from the method described in Conte, but that the process by which the claimed product is made will only hold patentable weight if the process imparts functional or structural limitations to the product that would distinguish it from the product of Conte. (*See*, Office Action at page 3).

Again, Applicants submit that the process by which the therapeutic tablet system required in claims 1-17 imparts functional and structural limitations to the claimed product that distinguish it from the product of Conte.

Applicants have amended claim 1, from which the remaining rejected claims properly depend, to require that the tablet in the claimed system, has a substantially constant active ingredient release rate. This, as stated by the Declaration by Ubaldo Conte submitted on January 29, 2009 and as admonished the Examiner in the outstanding Office Action, is different than the release profiles of Conte.

Applicants submit that the system of claims 1-17 imparts functional and/or structural limitations to the system that distinguish it from the product of Conte. Thus, Conte cannot anticipate claims 1-17. Reconsideration and withdrawal is requested.

Additionally, claims 1-17 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by US 6,599,284 (“Faour”). As stated above, in order to anticipate a claim, a reference must teach each and every element of the claim. (*See*, MPEP §2131). The Examiner indicates that Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, and an inner layer or core containing active ingredient, and the dosage form comprises a passageway formed by a incision, which is incised in both the top and bottom layers. (*See*, Office Action at page 5). Applicants traverse this rejection with respect to the claims as amended herein.

As discussed above, Applicants have amended claim 1, from which the remaining rejected claims properly depend, to require that the tablet in the claimed system has a substantially constant active ingredient release rate. As explained in the Declaration by Ubaldo Conte submitted on January 29, 2009 and acknowledged by the Examiner in the outstanding Office Action, is different than the release profiles of Conte.

Applicants re-submit that Faour teaches that the passageway increases the release rate of the active agent during use, which is different than that required by the current claims. (*See*, Faour at column 4, lines 48-50). This linear controlled rate required by claims 1-17 is achieved due to the incision on one face of the tablet, unlike in Faour where both the top and bottom layers are incised. Applicants submit that Faour does not teach each and every limitation of and thus cannot anticipate them. Reconsideration and withdrawal is requested.

Conte et al.
USSN: 10/507,345

On the basis of the foregoing amendment and remarks, Applicants respectfully submit that the pending claims are in condition for allowance, and a Notice of Allowance for the pending claims is respectfully requested. If there are any questions regarding this application that can be handled in a phone conference with Applicants' Attorneys, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



David E. Johnson, Reg. No. 41,874
Erica R. Carlson, Reg. No. 58,032
Attorneys for Applicants
MINTZ, LEVIN
Tel: 617-542-6000
Fax: 617-542-2241
Customer No. 30623

Date: September 16, 2009

ACTIVE 4712492v.1